



FOR US POSTAL SERVICE DELIVERY:

Office for Human Research Protections
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August 16, 2001

Norman Altman
Vice Provost for Research
University of Miami
1600 N.W. 10th Avenue (R-64)
Miami, FL 33101

Ira C. Clark
President
Public Health Trust
1611 N.W. 12th Avenue, W.W. 117
Miami, FL 33136

Gus Grady
Research Administrator
Veterans Affairs Medical Center
1201 N.W. 16th Street
Miami, FL 33125

**RE: Human Research Subject Protections Under Multiple Project Assurance
(MPA) M-1196**

Research Project: Southeastern Cancer Study Group (SEGU) Protocol # 240
PI: Dr. Howard E. Lessner

Dear Dr. Altman, Mr. Clark and Mr. Grady:

The Office for Human Research Protections (OHRP) has received your July 7, 2001 report regarding the above referenced research. OHRP acknowledges that although the University of Miami (UM) maintains protocol records as far back as 1980, no record of the complainant's involvement in a research protocol could be located at your institution nor the University of

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Miami Hospital and Clinics. OHRP finds that the allegation of failure to obtain and document legally effective informed consent as required under 45 CFR 46.116 and 117 cannot be substantiated. As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Maria J. Arnold, UM
Dr. AnnLynn Denker, Jackson Memorial Hospital
Dr. Jay M. Sosenko, IRB Chair, UM
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg Koski, OHRP
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Mr. George Gasparis, OHRP
Mr. Barry Bowman, OHRP